FREQUENTLY ASKED QUESTIONS
PHARMACEUTICAL MARKET ACCESS AND DRUG SAFETY ACT (S.334)

Why is this bill needed?
Under federal law, pharmaceutical companies are the only ones legally allowed to import prescription drugs approved by the Food and Drug Administration into the United States. While drug companies now import more than $40 billion in medicines into our country, U.S.-licensed pharmacists, drug wholesalers, and individual consumers are unable to likewise take advantage of the global marketplace.

As a result, American consumers are charged the highest prices in the world for the same medicines that are available in other major, industrialized nations at a fraction of the cost. For instance, Americans pay, on average, two-thirds more than the Canadians**,** 80 percent more than the Germans, 60 percent more than the British, 100 percent more than the French, and 112 percent more than the Italians.

This legislation would allow pharmacies, drug wholesalers, and individual consumers to import FDA-approved medicines from Canada and other developed countries with comparable regulatory regimes to benefit from the lower prices available on the world market. This opening up of trade will drive a re-pricing of prescription drugs here in the United States.

Who will be eligible to import prescription drugs under this legislation?
Licensed U.S. pharmacies and drug wholesalers that register with the Food and Drug Administration will be able to import prescription drugs for commercial re-sale. In addition, individual Americans will be allowed to purchase medicines directly from Canadian pharmacies under certain circumstances as described below.

How will American consumers be able to purchase medicines under this legislation?
Individual consumers will be able to purchase prescription medicines from registered Canadian pharmacies for their personal use or the personal use of a family member via mail-order or the Internet. The FDA will be required to make available on its website a list of the Canadian pharmacies that are approved to ship prescription drugs to Americans. Drugs imported by American consumers would have to be in a 90-day supply or less, accompanied by a valid prescription.

The bill also does not change the current practice of American consumers traveling to other countries such as Canada and Mexico and returning with a 90-day supply of medicine for their personal use, as allowed by the FDA's current "personal use" enforcement policy.

What prescription drugs can be imported under this legislation?
Only prescription drugs approved by the FDA and made in an FDA-inspected plant can be imported. Some prescription medicines that require special handling or storage or that pose special safety concerns could not be exported, such as controlled substances, infused or injected drugs, biologics, or drugs inhaled during surgery.

From what countries can medicines be imported?
U.S. pharmacies and drug wholesalers can import medicines from Canada and two dozen or more other major industrialized nations beginning in a year: the European Union, Australia, New Zealand, Japan, and Switzerland. These are countries that have drug approval and distribution systems similar to our own, and FDA is given the authority to add other countries with equivalent drug approval and distribution systems. Prescription drugs are already freely traded within the European Union, with no safety problems and, according to the *Wall Street Journal*, with savings to European countries and their citizens of $4.5 billion annually.

Individual Americans can purchase medicines from Canada via mail-order or the Internet from Canadian pharmacies registered with the FDA.

What are the safety features of this bill?
The basic approach to assuring the drugs are safe in this bill is to give FDA the ability to verify the drug pedigree back to the manufacturer, to require FDA to inspect frequently, and to require fees to give FDA the resources to do this.

For imports by individuals from Canada, our bill requires the exporters in Canada to register with FDA and to post a bond that they will lose if they send unsafe drugs. Frequent inspections by FDA ensure compliance.

For commercial imports, American wholesalers and pharmacists must register with FDA and are subject to criminal penalties if they import unsafe drugs. Again, frequent inspections by FDA ensure compliance.

The bill requires manufacturers to inform FDA whether foreign drugs meet FDA standards, and if they don't, the manufacturers have to give FDA the information necessary to evaluate the safety of the drug. If a foreign drug is manufactured in a plant the FDA hasn't inspected, FDA can inspect it.

FDA also gets better authority and the resources it needs to implement the drug importation program set up under this bill.

When will this legislation take effect?
The legislation will not be subject to a certification by the Secretary that importation poses no risk or that it will save money. That's not needed, because importation will be safe under the bill. We also know that importation saves money—that's why Americans all over the country are ordering drugs from Canada now. We also know that the certification is a poison pill that will kill importation.

Instead, importation by individuals from Canada via mail-order or the Internet would be legalized 90 days from enactment. Commercial importation from Canada and from other major industrialized countries in Europe, Switzerland, Australia, New Zealand, and Japan will begin after a year.

How is this bill similar to the Gutknecht-Vitter drug importation legislation, the Pharmaceutical Market Access Act (H.R. 328/S. 109)? How is it different?
In broad outline, the bills are similar. Wholesalers, pharmacies, and individuals can import drugs under either bill. Drugs can come from multiple major industrialized countries in addition to Canada under both bills. Wholesalers and pharmacies must register with FDA to be able to import under both bills. The drugs imported are supposed to meet FDA standards under both bills, and certain drugs, like controlled substances, are excluded from both bills. Both bills allow for drug importation to begin without first requiring certification by the Health and Human Services Secretary.

Like the bipartisan Dorgan-Snowe bill, the Gutknecht-Vitter bills also recognize the importance of strong provisions to prevent the drug companies from deterring importation by discriminating against suppliers that sell to Americans or suing them for patent violations.

The Dorgan-Snowe bill, however, provides additional assurances that the imported drugs will be safe. We require frequent FDA inspections of importers and exporters, verification of the chain of custody of each drug imported, and provide the resources FDA needs to do the job.

How is this bill different from the bill Senator Gregg introduced, the Safe Importation of Medical Products and other RX Therapies Act (S. 184)?
Unlike the bipartisan bill, the Gregg bill does not include any non-discrimination provisions to prevent drug companies from thwarting drug importation, such as by shutting off the supplies of their drugs to pharmacies that sell to Americans, as they are currently doing in Canada. In addition, the Gregg bill falsely assumes that, if drug companies do cut off Canadian wholesalers and pharmacists, then Canadians can access drug supplies from the European Union via trans-shipment. However, trans-shipment is illegal under Canadian law.

The Gregg bill is likely to result in only limited savings for American consumers because it limits drug importation to Canada only for at least the first three years. After 3 years, the FDA could allow imports from Europe, but only if FDA first certifies that imports from Europe "would not present an increased risk to the public health." Since FDA has been unwilling to make a similar certification with respect to Canada, it seems highly unlikely that FDA would allow drug imports from Europe. The Congressional Budget Office has said a Canada-only approach would result in only small savings for Americans. Under the Dorgan-Snowe bill, commercial drug importation would be allowed from Canada and two dozen or more developed nations after 1 year, ensuring real savings for U.S. consumers.

Finally, there are a number of safety concerns posed by the Gregg bill. For instance, unlike the Dorgan-Snowe bill, there is no mechanism in the Gregg bill for the FDA or an importer to know whether a drug distributed in another country meets FDA approval requirements or not. In addition, the Gregg bill does not require FDA inspection of Internet pharmacies, while the Dorgan-Snowe bill requires frequent, random FDA inspection of Canadian pharmacies, including those marketing their drugs via the Internet. Likewise, the Gregg bill does not require inspections of commercial drug shipments, does not authorize inspection of other entities in the chain of custody, and only permits inspection of records if FDA has

"reason to believe" that an imported drug "presents a risk to public health." The Dorgan-Snowe bill requires frequent FDA inspection of importers and provides FDA with the authority to inspect records and other entities in the chain of custody.

How much does the bipartisan bill cost and how would it be paid for?
The Congressional Budget Office has not yet scored this bill. However, the costs associated with establishing the drug importation safety system created under this bill would be fully financed by user fees on registered importers and Canadian exporters. These fees would be capped at 1 percent of the total value of drugs imported annually to the United States in order to ensure that this fee does not become unduly burdensome or cost prohibitive for registered importers and Canadian exporters. There are currently about 40 Canadian pharmacies supplying most of the $1 billion in drugs now being imported from Canada; the 1 percent user fee works out to $250,000 per Canadian pharmacy, which should be more than adequate to pay for FDA inspection.

In addition, drug manufacturers would bear the additional costs associated with the need for FDA approval of the changes they might make to their products in an effort to thwart drug importation.

How do you respond to those who say that drug importation won't generate much savings?
The House-passed Pharmaceutical Market Access Act was scored by the Congressional Budget Office as reducing total drug spending by $40 billion over 10 years. In its cost estimate, CBO assumed that drug companies and foreign governments would take actions to limit the volume of medicines that could be imported to the U.S., thus limiting the savings. Although the savings generated by the House-passed bill are nothing to sneeze at, we would expect the bipartisan Senate bill to generate even larger savings for American consumers and other drug purchasers. That's because the bipartisan Senate bill includes strong provisions to prevent drug companies from cutting off drug supplies in foreign countries, thereby removing the incentive for foreign governments to prevent importation due to fear of drug shortages in their own country.

How can we be sure that savings realized by pharmacists and wholesalers will be passed along to consumers?
The pharmacy marketplace is highly competitive and will ensure that the savings are passed along. Community pharmacies generally have modest gross margins and low profits. In addition, their customers who do not have insurance coverage for prescription drugs are extremely price sensitive and will take their business to mail-order companies or elsewhere if the lower prices are not passed on. Their customers will also have the option of purchasing their medicines directly from Canada if their local pharmacy does not share the savings with them.
As a result, pharmacists will have little choice but to pass the lower prices on to their customers.

If drug wholesalers do not pass the savings along to pharmacies, individual pharmacies or groups of pharmacies will import the prescription medicines themselves in order to pass the savings along to their customers.

Won't drug companies just prevent drug importation by shutting down the drug supply or by making changes to the drug (such as a change in color or place of manufacture) to render it unapproved?
We know that Pfizer, Glaxo Smith Kline, Eli Lilly and others are already shutting off supply of drugs to those in Canada that export drugs to American consumers. Such tactics will be an unfair and discriminatory practice under our bill, subject to treble damages. Treble damages should deter such behavior by the drug companies.

In addition, the bipartisan bill requires drug companies to tell FDA if the drugs they distribute overseas are the same as or different than the FDA-approved drugs they distribute domestically. Most likely, foreign drugs will be the same, but when they are different or when the drug companies change their foreign drugs to thwart importation, FDA is given the authority to review and approve those differences.

How do you respond to some who say this bill would import other countries' price controls?
The Pharmaceutical Market Access and Drug Safety Act merely extends the benefits of free trade to buyers of prescription drugs. Drug manufacturers already benefit from the fact that many of the active ingredients imported into the United States that are used to produce pharmaceuticals enter free of duty. And these ingredients are available at low world market prices. This bill would simply enable American consumers to make the global economy work for them, too. Drug manufacturers today are charging higher prices to Americans for drugs than they charge to patients in other countries and using laws designed to assure health and safety to maintain price discrimination.

How do you respond to those who claim that the bipartisan bill contains unconstitutional "forced sales" provisions?
Under the bipartisan bill, if a drug company chooses to sell prescription drugs in a foreign country at the prices in that country, then the company can't discriminate against firms that import medicines to the U.S. from that country. Such a provision is crucial to ensuring that big drug companies don't cut off the supply of drugs to pharmacies that are selling to the U.S. However, as the bill language makes clear, nothing in the bipartisan bill compels a drug manufacturer to distribute or sell its drugs in a country.

Drug industry attorneys always say that legislation to reduce the cost of drugs for consumers violates the Constitution, but objective legal authorities say the bipartisan bill is constitutional.

How do you respond to concerns that liability costs will make prescription drug importation cost prohibitive?
Such a concern is based on the faulty premise that prescription drugs imported under the Pharmaceutical Market Access and Drug Safety Act are somehow less safe and effective. Nothing could be further from the truth. The drugs imported under the bipartisan bill will be FDA-approved and will have to meet the same standards of safety and effectiveness. In fact, imported drugs may even be safer than those currently available in the United States because importers will have to document their

chain-of-custody from the point of manufacture to the drugstore shelf – a requirement that drugs sold domestically in the United States currently do not meet.

Why is the relationship between legalized prescription drug importation in the bill and a drug maker's patent rights?

Under current U.S. law, if the first authorized sale of a patented pharmaceutical occurs outside the United States, the patent holder (the drug manufacturer) can prohibit the subsequent importation of that pharmaceutical into the United States. The bill changes U.S. law so that the patent holder can no longer prohibit importation into the United States once there has been an authorized first sale of the patented pharmaceutical outside the United States. In other words, the bill changes U.S. law so that a drug maker's right to prohibit importation of a patented pharmaceutical product is exhausted once the drug maker authorizes a first sale of the pharmaceutical outside the United States. As a result of this change in patent law, parallel trade in prescription drugs may occur under the bill without infringing upon a drug maker's patent rights.

The WTO Agreement on Trade-Related Intellectual Property Rights (TRIPS) provides that nothing in TRIPS shall be used to address the issue of exhaustion of intellectual property rights, as long as a WTO member's rule for patent exhaustion is applied to all WTO members equally. The rule of international first-sale patent exhaustion in the bill does not discriminate against WTO members, so as to avoid potential litigation in the WTO. In fact, according to independent analysis prepared by the Congressional Research Service, the rule of international first-sale patent exhaustion included in the bill does not violate TRIPS. The European Union already applies a rule of international first-sale patent exhaustion that has resulted in a flourishing parallel trade in prescription drugs among EU member states.

How do you respond to the claims by the pharmaceutical industry that this bill will cut into the amount they spend on research?

A recent study by the Boston University School of Public Health has found that drug imports may not hurt drug company profits at all because it would spur an increase in the use of medicines.

Drug companies must innovate to survive, so it's hard to see why they would reduce what they do to innovate. Certainly, the drug companies will still have the resources to support research and development (R&D). Only about 20 cents of each prescription drug dollar is spent on research and development, and profits exceed research costs at the top ten U.S. drug companies. Pharmaceutical companies' after-tax profits—and after expenditures for R&D—averaged 17 percent from 1994 to 1998, compared with 5 percent for all other industries, according to a December, 1999, report from the Congressional Research Service. The drug industry has been the most profitable industry over the last 10 years.

The drug industry also spends a significant portion of their budgets—$15.7 billion in 2000—on product promotion. In fact, according to an April 2002 analysis by Public Citizen, Fortune 500 pharmaceutical companies spent nearly three times more on marketing, advertising, and administration than they did on R&D. Yet, the pharmaceutical industry never talks about needing to cut back on drug advertising.

In addition, American taxpayers heavily subsidize pharmaceutical research both through the tax code and research at the National Institutes of Health. For instance, according to the CRS, drugmakers pay significantly less in taxes than other industries: The average effective tax rate for pharmaceutical companies was 16.2 percent from 1993 to 1996, compared to the average effective tax rate of 27.3 percent for all other major industries. Moreover, NIH research contributed to the development of 15 of the 21 most important prescription drugs introduced between 1965 and 1992.